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BriaCell Therapeutics Corp. (BCTX: NASDAQ)

Fiscal Year 2022 Results

Based on our DCF model and a 15% discount rate, BriaCell is valued at approximately $15.00 per share. With regard to regulatory approval and commercialization, our model applies a success probability of 20% for BRIA-IMT and 8% for Bria-OTS in advanced breast cancer. The model includes contributions from the United States and rest of world.

Current Price (10/28/2022)	$5.43
Valuation	**$15.00**

OUTLOOK

BriaCell Therapeutics is a clinical stage oncology-focused biotechnology company using cell-based immunotherapies to target breast and other cancers. The approach stimulates a cancer fighting immune response to destroy tumor cells. Lead candidate Bria-IMT™ is advancing in combination with other therapies including checkpoint inhibitors to combat breast cancer. Secondary candidate Bria-OTS™ addresses variation between patients with breast cancer and is based on a patient's human leukocyte antigen (HLA) type. If successful, this product could address almost all third-line patients.

In addition to Bria-IMT and Bria-OTS, the company offers a portfolio of other preclinical assets addressing prostate, non-small cell lung, melanoma and other cancers. In clinical work to date, BriaCell has shown a strong correlation between the efficacy of Bria-IMT and patients that have a close HLA match with the therapeutic cells.

BriaCell is conducting a Phase I/IIa combination study and has released interim data demonstrating effective immune response and disease control in heavily pre-treated patients. We anticipate start of a pivotal trial in 2023 and BLA submission to regulatory authorities in 2025.

SUMMARY DATA

52-Week High	**12.47**
52-Week Low	**4.06**
One-Year Return (%)	**-30.0**
Beta	**1.45**
Average Daily Volume (sh)	**418,256**
Shares Outstanding (mil)	**15.5**
Market Capitalization ($mil)	**84.2**
Short Interest Ratio (days)	**2.94**
Institutional Ownership (%)	**15.6**
Insider Ownership (%)	**25.0**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2022 Estimate	**N/A**
P/E using 2023 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue

(In millions of USD)

	Q1 (Oct)	Q2 (Jan)	Q3 (Apr)	Q4 (Jul)	Year (Jul)
2021	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2022	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2023					$0.0 E
2024					$0.0 E

Earnings per Share

	Q1 (Oct)	Q2 (Jan)	Q3 (Apr)	Q4 (Jul)	Year (Jul)
2021	-$0.54 A	-$0.30 A	$0.63 A	-$0.24 A	-$0.09 A
2022	-$0.16 A	-$0.24 A	-$0.32 A	-$1.05 A	-$1.73 A
2023					-$1.28 E
2024					-$1.36 E

*FY:21 EPS does not sum to annual due to large increase in share count in 2H:21.

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WHAT'S NEW

Fourth Quarter Fiscal Year 2022 Operational and Financial Results

On October 28th 2022, BriaCell Therapeutics Corp. (NASDAQ: BCTX) published fiscal year 2022 financial and operational results in its first Form 10-K filing with the SEC as it no longer qualifies as a foreign private issuer. BriaCell has most recently entered into multiple agreements with partners to advance its oncology programs, presented at several conferences and completed the Phase I portion of its advanced breast cancer evaluation of Bria-IMT in combination with Incyte's retifanlimab. Looking ahead, the company will present new data at the 2022 Society for Immunotherapy of Cancer (SITC) Annual Meeting in November and at the 2022 San Antonio Breast Cancer Symposium in early December.

Highlights for calendar year 2022 include:

- Results of 2022 Annual and Special Meeting of Shareholders - January 2022
- Buyback and insider buying update - February 2022
- Giuseppe Del Priore, M.D., MPH, appointed Chief Medical Officer - February 2022
- Alexander Kharazi, M.D., Ph.D., appointed to Scientific Advisory Board - February 2022
- Additional clinical trial sites added to accelerate patient enrollment – February/May 2022
- Establishment of Philadelphia Lab – 1H:22
- Bria-OTS presentation at AACR – April 2022
- Grant of Fast Track status to Bria-IMT – April 2022
- Partnership secured with Waisman Biomanufacturing for Bria-Pros – July 2022
- License granted for New Anti-Cancer Agent, Soluble CD80 – August 2022
- Partnership signed with Caris Life Sciences for patient outreach/molecular profiling – September 2022
- Completion of Phase I Bria-IMT safety study – October 2022

BriaCell produced no revenues for fiscal year 2022 and incurred operating expense totaling ($15.3) million and an ($11.6) million charge representing a change in fair value for the warrant liability which produced a net loss of ($26.8) million, or ($1.73) per share.

For the fiscal year ending July 31, 2022 versus the same ending July 31, 2021:

- Research & development expense was $8.0 million, up considerably from $2.0 million,[1] attributed to the resumption of clinical trials and increased laboratory activity, including the hiring of additional employees;
- General & administrative expenses totaled $7.3 million, up from $5.0 million, due to greater expenses related to share-based compensation, increases in salaries due to hiring more personnel and recognition of consulting and professional fees;
- Financial expenses totaled $11.5 million, an amount predominantly composed of a change in fair value of warrants with small offsets from interest income and gain on a government grant among other minor items;
- Net loss totaled ($26.8) million vs. ($428,000), or ($1.73) and ($0.09), respectively. Excluding the impact of non-operational items, net loss was ($15.3) million or ($0.99) per share.

As of July 31, 2022, cash and equivalents totaled $41.0 million compared to $57.3 million at the end of the fiscal year last July. Cash used in operations was ($12.5) million for FY:22. Cash burn year to date totaled ($9.2) million. Financing cash flows consumed ($3.7) million and were dominated by share and warrant repurchase program outflows and repayment of a government grant partially offset by proceeds from exercise of warrants.

[1] Note that prior year comparisons discussed herein reflect GAAP accounting rules and do not match results as originally reported.

Operational Update

Since our last update in June, BriaCell has published data in the journal *Anti-Cancer Drug Discovery* on Bria-IMT emphasizing the company's approach to developing cellular immunotherapies for cancer and the drug's mechanism of action. The article is titled "Regression of Breast Cancer Metastases Following Treatment with Irradiated SV-BR-1-GM, a GM-CSF Overexpressing Breast Cancer Cell Line: Intellectual Property and Immune Markers of Response." A collaboration with Harvard Medical School that aims to discover new anti-cancer targets was executed in late June. The research collaboration will focus on the discovery and development of novel targets to enhance tumor cell responsiveness to chemotherapy and immunotherapies in specific cancers including lung, head and neck, cervical, and bladder cancers. Results from the collaboration are expected to help develop insights into research and development efforts at BriaCell.

The development of new intellectual property extended to the acquisition of a license to develop and commercialize Soluble CD80 (sCD80) as a biologic agent for the treatment of cancer. Several patents under the title "Soluble CD80 as a Therapeutic to Reverse Immune Suppression in Cancer Patients" provide protection for the intellectual property. The invention provides for a therapeutic cancer treatment using a soluble CD80 fusion protein that binds to programmed death ligand 1 (PD-L1) and inhibits PD-L1 and PD-1 interactions thereby overcoming immune suppression and restoring T cell activation.

BriaCell joins with Caris Life Sciences to improve efficiency of patient identification to help in its enrollment of its Bria-IMT Phase II clinical trial. Caris has relationships with almost 500 oncology sites that can identify and enroll eligible patients in biomarker-directed clinical trials based on inclusion and exclusion criteria. Caris also offers comprehensive molecular profiling that can examine the whole exome and whole transcriptome sequencing that will enable tumor profiling for enrolled patients.

Phase I/IIa Bria-IMT + Retifanlimab + Epacadostat (NCT03328026)

BriaCell's ongoing Phase I/IIa clinical trial is actively enrolling patients in advanced breast cancer. Updates on safety and efficacy are expected throughout 2022. BriaCell most recently reported that it had completed the Phase I portion of the trial with enrollment of 12 subjects. Additionally, the company reports that another arm has recently been added to the Phase II study to evaluate the effects of dosing schedules.

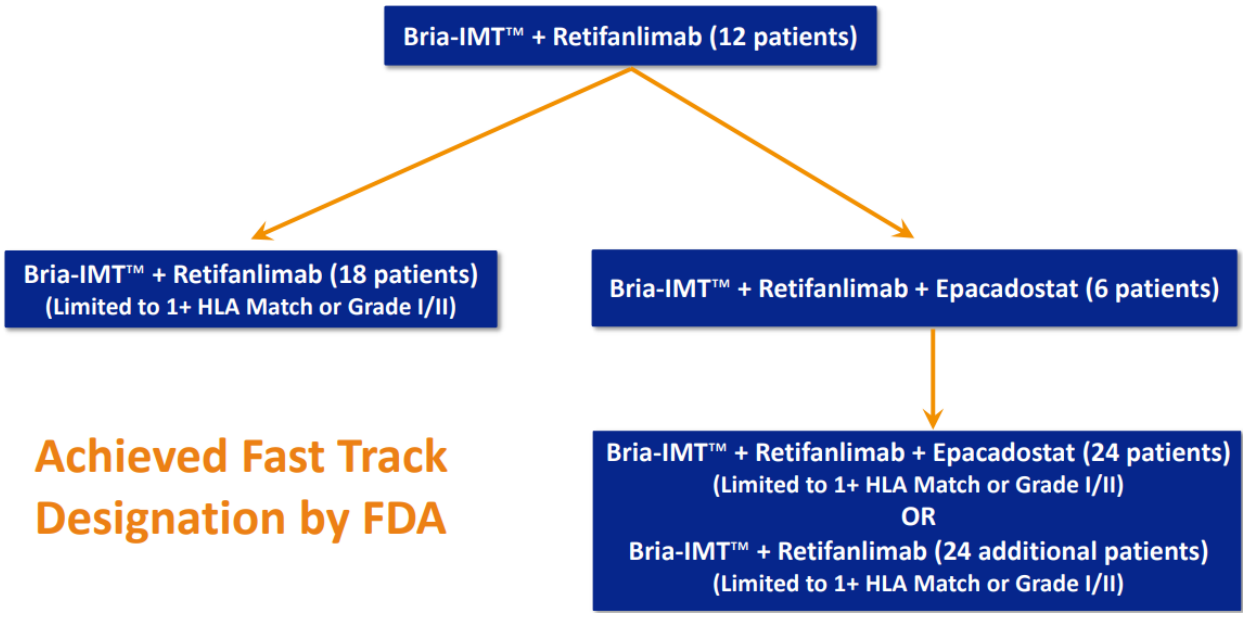
The trial is investigating Bria-IMT in combination with Incyte's checkpoint inhibitor retifanlimab and epacadostat. Fast track status was granted by the FDA in mid-April. The status should increase the frequency of meetings between BriaCell and the FDA and open the door for other programs including Accelerated Approval, Priority Review and Rolling Review if appropriate.

Additional Clinical Trial Sites Added
To date, BriaCell has added five new trial sites in 2022, with the most recent addition of the Mayo Clinic in Jacksonville, Florida expected to accelerate enrollment in the Bria-IMT breast cancer trial. This brings the total number of sites in the study to eight.[2]

Bria-IMT along with an anti-PD-1 antibody[3] and IDO1[4] inhibitor epacadostat[5] is being investigated using a combination approach in breast cancer patients that have failed two or more prior lines of therapy. The regimen includes a pre-dose of the chemotherapy cyclophosphamide and post-dose antiviral interferon-α2b. Late last year, 12 patients were evaluated and additional patients were added at the new sites announced. In a previous update, three of four patients with grade I/II tumors attained disease control. As highlighted in a December 2021 poster presentation at the San Antonio Breast Cancer Symposium, disease control was 33% in the combination study. Complete tumor reduction of selected tumors was observed in several patients, including those with two or more HLA matches with Bria-IMT and Grade I/II tumors. For the evaluable Grade I/II patients, disease control was seen in three of four patients in the combination study.

[2] Sites include Mary Crowley Cancer Research Center, Dallas, Texas; Providence Medical Group, Santa Rosa, California; Cancer Center of Kansas, Wichita, Kansas, Atlantic Health System, Tranquil Clinical Research, Hoag Memorial Hospital Presbyterian, St. Joseph Heritage Healthcare, Sylvester Comprehensive Cancer Center, Overlook Medical Center and Mayo Clinic in Jacksonville, Florida,
[3] The trial has used Incyte/Macrogenics' retifanlimab and Merck's Keytruda in the role of PD-1 inhibitor.
[4] IDO: indoleamine 2,3-dioxygenase
[5] Epacadostat targets and binds to IDO1, an enzyme responsible for the oxidation of tryptophan into kynurenine. By inhibiting IDO1 and decreasing kynurenine in tumor cells, epacadostat increases and restores the proliferation and activation of various immune cells, including dendritic cells (DCs), NK cells, and T-lymphocytes, as well as interferon (IFN) production, and a reduction in tumor-associated regulatory T cells (Tregs). (Source: NIH Drug Dictionary)

Exhibit I - Bria-IMT™ Phase I/IIa Ongoing Combination Therapy Trial Design[6]



Bria-OTS

Bria-OTS cell lines are being engineered and transferred to good manufacturing practice (GMP) production and undergoing clinical evaluation this year. FDA investigational new drug clearance and dosing of the first patient is expected to occur prior to the end of 2022 with safety and efficacy data expected to be released in the subsequent months. Bria-OTS is also working with the National Cancer Institute (NCI) on characterization of the product in the lab and is progressing as expected. The NCI project has a three-year duration and expected to complete in October of 2023.

Exhibit II - BriaCell Clinical Pipeline[7]

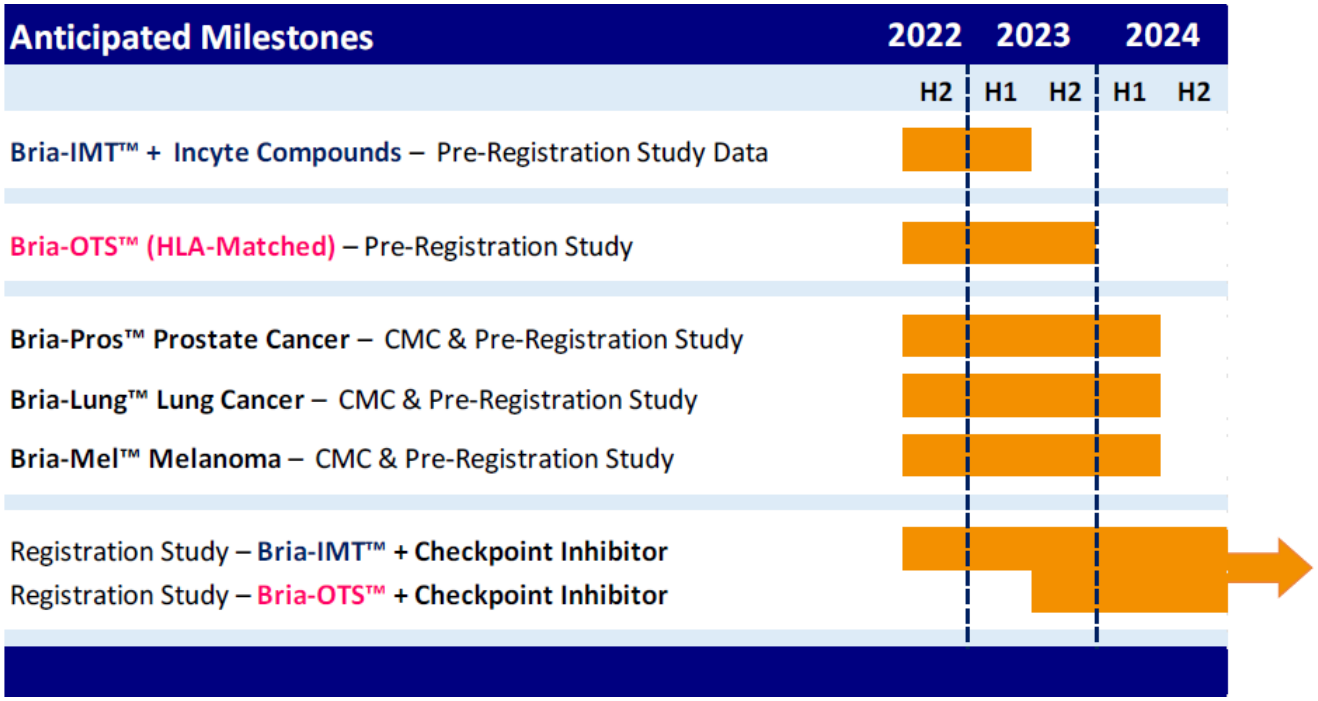
Therapeutic	Indication	Preclinical	Phase I	Phase II	Phase III	Anticipated Milestones
Bria-IMT™ combined with Incyte's retifanlimab	Advanced Breast Cancer (3rd+ line)	Ph I/II (Fast Track)				Safety & Efficacy Data 2H2022 Registration Study 2H2022
Bria-OTS™	Breast Cancer					IND Filing 2H2022
Bria-Pros™	Prostate Cancer					IND Preparation 2H2022
Bria-Lung™	Non-Small Cell Lung Cancer					IND Preparation 2H2022
Bria-Mel™	Melanoma					IND Preparation 2H2022
sCD80	Solid Tumors					IND Filing 2024
Bria-TILsRx™	Prostate Cancer					IND Filing 2024
Bria-TILsRx™	Epithelial and Glandular					IND Filing 2024
PKCδi*	RAS Transformed Cancers					Candidate Selection 2022

[6] BriaCell Investor Presentation Summer 2022
[7] BriaCell Investor Presentation September 2022. *PKCδi = Protein kinase C delta inhibitor

Upcoming Milestones

- Bria-IMT End of Phase II meeting with FDA – 4Q:22 / 1Q:23
- Candidate selection for PKCδ – 2H:22
- Presentation at 2022 Society for Immunotherapy of Cancer (SITC) – November 2022
- Presentation at 2022 San Antonio Breast Cancer Symposium – December 2022
- Registration study for Bria-IMT – 1Q:23
- Presentation at AACR Bria-OTS NCI data – April 2023
- Completion of the Bria-OTS NCI project – October 2023

Exhibit III – Development Timeline and Catalysts[8]



Summary

Fiscal year 2022 saw a dramatic increase in spending for BriaCell as fundraising completed in 2021 was translated into an increase in clinical trial and operational activity. Several new trial sites were opened, new executives and board members were added and the company increased its interaction with the FDA to support and guide the acceleration in research and development activity. Interaction with the investment and scientific community was emphasized in 2022 with participation at the San Antonio Breast Cancer Symposium, SITC and AACR recently highlighted. Most importantly, BriaCell announced that it had completed the Phase I portion of its combination advanced breast cancer trial and that Bria-IMT had demonstrated a favorable safety profile in combination with retifanlimab.

As BriaCell advances the Phase II portion of its clinical work, we expect the company to compare the effectiveness of different dosing schedules with results expected next year. Secondary candidate Bria-OTS is expected to be the subject of additional evaluation work over the following months. We anticipate start of a registrational trial in 2023 and BLA submission to regulatory authorities in 2025. Based on our analysis of Bria-IMT and Bria-OTS and the clinical trial data generated to date, we see a pathway forward to commercialize this cell-based targeted immunotherapy. We maintain our target price of $15.00 per share.

[8] BriaCell Investor Presentation September 2022

PROJECTED FINANCIALS

BriaCell Therapeutics Corp. – Income Statement[9]

BriaCell Therapeutics Corp	2021 A	Q1 A	Q2 A	Q3 A	Q4 A	2022 A	2023 E	2024 E
Total Revenues ($USD)	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
Research & Development	$1,315	$876	$1,734	$2,543	$2,869	$8,021	$14,852	$18,945
General & Administrative	$3,690	$891	$2,199	$2,302	$1,875	$7,267	$4,100	$4,500
Share Based Compensation	$1,968	$518	$0	$0	$0	$0	$1,200	$1,200
Income from operations	($6,973)	($2,285)	($3,932)	($4,846)	($4,744)	($15,289)	($20,152)	($24,645)
Other Items	$6,545	($101)	$67	$6	($11,522)	($11,550)	$0	$0
Pre-Tax Income	($428)	($2,386)	($3,865)	($4,839)	($16,266)	($26,839)	($20,152)	($24,645)
Provision for Income Tax	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Net Income	**($428)**	**($2,386)**	**($3,865)**	**($4,839)**	**($16,266)**	**($26,839)**	**($20,152)**	**($24,645)**
Reported EPS	**($0.09)**	**($0.16)**	**($0.24)**	**($0.32)**	**($1.05)**	**($1.73)**	**($1.28)**	**($1.36)**
Basic Shares Outstanding	4,520	15,239	15,789	15,359	15,518	15,494	15,750	18,100

Source: Company Filing // Zacks Investment Research, Inc. Estimates

[9] Financial statement information presents data as originally reported.

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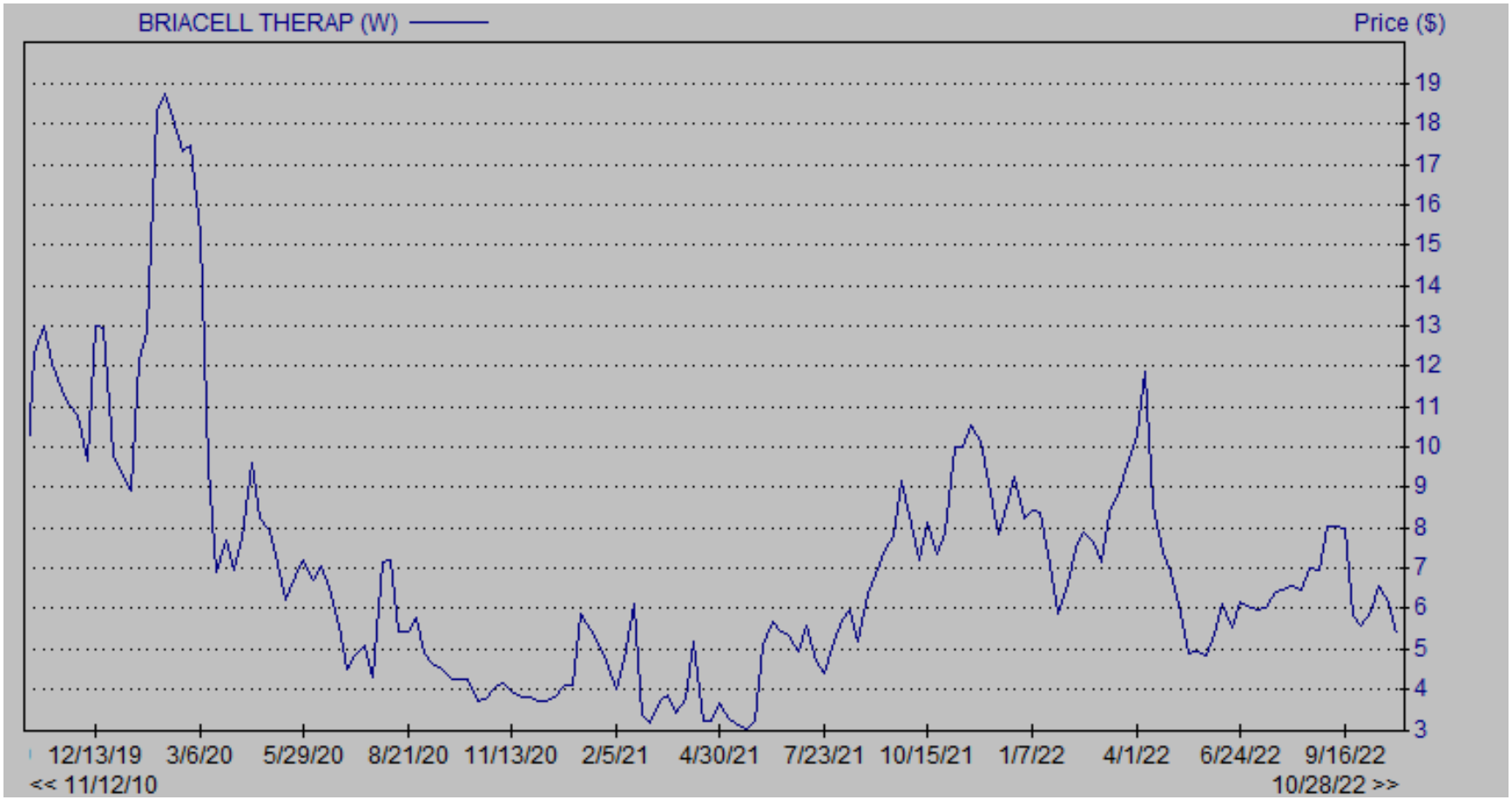
HISTORICAL STOCK PRICE

BriaCell Therapeutics Corp. – Share Price Chart[10]



[10] Source: Zacks Research System

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